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## **Can CAM treatments be evidence-based?**

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### **Abstract**

In this essay, we first take a critical look at the definitions of evidence-based medicine (EBM) and complementary and alternative medicine (CAM). We then explore the question of whether there can be evidence-based forms of CAM. With the help of three examples, we show that EBM and CAM are not opposites, but rather concepts pointing at different dimensions. Each of the three examples is an evidence-based treatment according to three to five randomized, double-blind placebo controlled trials with consistent findings and narrow pooled confidence intervals. The most reasonable interpretation for the existence of evidence-based CAM treatments seems to be that the opposite of CAM is ‘mainstream medicine’, and the demarcation line between CAM and mainstream medicine is not defined by the question of whether a treatment works or not. Some effective treatments may belong to the CAM field for historical reasons and because of preconceptions within mainstream medicine. Therefore, some treatments that currently lie outside mainstream medicine can be evidence-based.

In 2004, the journal Evidence-Based Complementary and Alternative Medicine (eCAM) was launched. According to its website, it ‘seeks to understand the sources and to encourage rigorous research in this new, yet ancient world of complementary and alternative medicine.’<sup>1</sup>

eCAM is an open access journal that published over 1000 papers in 2013.

This new combination of ‘evidence-based medicine’ (EBM) and ‘complementary and alternative medicine’ (CAM) is interesting, but we find it strange that the journal does not provide any definition or explanation of the two terms. Both terms have many meanings, and their combination can also be understood in numerous ways.

The aim of this essay is to look at the definitions of EBM and CAM and then explore the question of whether there can be evidence-based forms of CAM.

### **What is EBM?**

The term evidence-based medicine (EBM) appeared initially in an information document aimed at prospective or new students at the McMaster University in Canada in the autumn of 1990.<sup>2</sup> McMaster was the home of a group of physicians who demanded that clinical decisions be based on ‘best evidence’.

The concept EBM was introduced to the wide medical community in JAMA in 1992.<sup>3</sup> EBM was promoted as ‘a new approach to teaching the practice of medicine’ and a ‘new paradigm of medical practice’. No specific definition was given in the article, but according to it EBM ‘de-emphasizes intuition, unsystematic clinical experience, and pathophysiologic rationale as sufficient grounds for clinical decision-making and stresses the evidence from clinical research’. In particular, the 1992 paper instructed clinicians to search for studies with the question ‘Was the assignment of patients to treatments randomized?’ The article was a bold programme statement that divided the medical world into the old-fashioned pre-EBM and the revolutionary new EBM types of medicine.

A rather general definition of EBM was formulated four years later:

Evidence-based medicine is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients.<sup>4</sup>

This has remained the most widely cited definition of EBM. Nevertheless, it is not a surprise that the medical world did not unanimously welcome this new programme. A few years later, Charlton and Miles published a paper titled ‘The Rise and Fall of EBM’, in which they sharply criticised the EBM approach.<sup>5</sup> Another critic, Mark Tonelli, noted that there is certainly not a physician alive

who would not claim to practise EBM when it is defined as the ‘conscientious, explicit and judicious use of current best evidence in making decisions’.<sup>6</sup> The above a definition of EBM is so vague that it does not provide any *demarcation line* between EBM and non-EBM.

Later, other definitions of EBM have been proposed such as:

EBM is currently understood to incorporate clinical epidemiological data, meaningful deliberations of professionals’ pathophysiological knowledge and clinical experience, together with patient preferences.<sup>7</sup>

...the evidence to which EBM refers to ought to comprise six dimensions: scientific evidence, theoretic evidence, practical evidence, expert evidence, judicial evidence and ethics-based evidence.<sup>8</sup>

These definitions demonstrate the multitude of meanings that term EBM has nowadays.

They also raise the question of whether there is any actual difference between EBM and pre-EBM, since all six dimensions were important issues in mainstream medicine also before 1992.

In 2005 Timmermans and Mauck wrote sarcastically that

The term [EBM] is loosely used and can refer to anything from conducting a statistical meta-analysis of accumulated research, to promoting randomized clinical trials, to supporting uniform reporting styles for research, to a personal orientation toward critical self-evaluation.<sup>9</sup>

Despite the disagreements and confusions about the basic definitions, one aspect in the EBM programme has been particularly essential since the introduction of the term in JAMA in 1992, namely, the view of valid evidence: ‘comparative clinical studies, preferably from *randomized trials* [RCTs], are deemed to provide better evidence than mechanistic reasoning and clinical experience.’<sup>2,3</sup> [our italics]

## **What is CAM?**

CAM is an acronym combining two terms, ‘complementary medicine’ and ‘alternative medicine’, neither of which is ancient. According to PubMed, ‘alternative medicine’ first appeared in medical journals in 1975 and ‘complementary medicine’ in 1985.<sup>10</sup>

The former term dates back to the alternative lifestyle movement that originated in the United States in the late 1960s.<sup>10,11</sup> The latter term was adopted in Britain with the political objective of raising the question of whether medicine could include some of the alternative healing practices in its tool kit.<sup>10</sup>

A further related term, ‘integrative medicine’, was introduced in the 1990s in order to suggest a deeper marriage between alternative treatments and medicine.<sup>10</sup>

The meanings of ‘alternative’ in ‘alternative medicine’ or ‘complementary’ in ‘complementary medicine’ have not been properly explained, and it is common that their supporters present ‘official’ medicine as a rigid and closed system that is full of prejudices. ‘Alternative’ and ‘complementary’ are often used as buzzwords, important-sounding phrases ‘of little meaning used chiefly to impress laymen’.<sup>12</sup> The proponents of CAM often use other buzzwords like ‘natural’ or ‘holistic’, the meanings of which are vague.<sup>11,13</sup>

Wolpe has suggested that CAM is best understood as a ‘residual category’, which means that it is defined by its exclusion from ‘official’ or ‘medical school’ medicine, which we call ‘mainstream medicine’ in this essay.<sup>14</sup>

The Committee on the Use of Complementary and Alternative Medicine of the American Public Board on Health Promotion and Disease Prevention defined CAM as

... a broad domain of resources that encompasses health systems, modalities, and practices and their accompanying theories and beliefs, other than those intrinsic to the dominant health system of a particular society or culture in a given historical period. CAM includes such resources perceived by their users as associated with positive health outcomes. Boundaries within CAM and between the CAM domain and the domain of the dominant system are not always sharp or fixed.<sup>15</sup>

Like the definitions of EBM, the preceding definition is too vague to provide even a rough *demarcation line* between CAM and the ‘dominant system’. It is, however, an important description in pointing out the diversity of the phenomena behind the concept. This complexity also explains why the boundaries between the CAM domain and mainstream medicine are not sharp or constant.

The meanings of CAM and ‘alternative medicine’ largely overlap, and, for the purposes of this essay, we use the short and pragmatic definition of the latter that was used in 1998 in a study on national trends on the use of alternative medicine in the United States:

Alternative medical therapies, functionally defined as interventions  
neither taught widely in medical schools nor generally available in US hospitals...<sup>16</sup>

Although such a sociological definition has its own problems, we consider it to be the most useful definition for the purpose of our essay.

### Are there EBM treatments in the CAM field?

Thus EBM and CAM are both rather vague terms that escape rigorous definitions. Here we take a pragmatic approach and consider CAM to mean therapies that lie outside mainstream medicine. We also consider the most fundamental principle of EBM to be the requirement that treatments are based on RCTs. Thus various treatments can be arranged simultaneously into a  $2 \times 2$  table on the basis of both concepts as shown in Table 1.

**Table 1.** Treatments according to the EBM and CAM concepts

	Mainstream medicine	CAM
EBM (treatments based on RCTs)	<b>1</b>	<b>3</b>
Not EBM (treatments not based on RCTs)	<b>2</b>	<b>4</b>

Cell 1 in Table 1 covers treatments in mainstream medicine that are based on numerous large RCTs (e.g., treatments of hypertension and myocardial infarction).

Cell 2 covers mainstream medicine treatments that are not based on RCTs. It not only includes potentially ineffective treatments that are used for historical reasons, but also treatments that cannot be examined with RCTs because of practical or ethical reasons (e.g. antibiotics for severe bacterial infections, volume replacement therapy in severe bleeding). Such treatments are justified on the basis of ‘mechanistic reasoning and clinical experience’, which are discouraged by the proponents of EBM.<sup>3</sup> Thus Cell 2 is a mixed collection of valid treatments (though not based on RCTs) and potentially ineffective treatments.

For this essay, the most interesting part of Table 1 is Cell 3. Are there treatments that are based on RCTs but lie outside mainstream medicine? If we argue that a treatment falls into Cell 3, we must first prove that the treatment belongs to the CAM field, and, second, there must be consistently positive findings in RCTs that justify the conclusion that the treatment is effective.

Vitamins and minerals are commonly classified as a form of CAM. For example, the National Center for Complementary and Alternative Medicine (NCCAM), which is part of the National Institutes of Health in the United States, states on its website that ‘Natural [CAM] Products’ include ‘vitamins and minerals ... They are widely marketed, readily available to consumers, and often sold as dietary supplements.’<sup>17</sup> Specifically, according to the NCCAM, vitamin C and zinc for the common cold falls into the CAM category<sup>18</sup>, as does vitamin C for asthma.<sup>19</sup> The Cochrane Library also classifies these three treatments as CAM treatments.<sup>20</sup> We suggest that there is strong evidence for the efficacy of these three treatments. In our view, they are examples of treatments that fall into Cell 3 in Table 1.

In three RCTs, high-dose zinc acetate lozenges shortened the duration of colds by 42% (95% CI: 35% to 48%).<sup>21</sup> In five RCTs vitamin C administration reduced the incidence of cold symptoms in people under short-term physical stress by 48% (95% CI: 35% to 64%).<sup>22</sup> Finally, in three RCTs, vitamin C administration was beneficial for patients with exercise-induced asthma since it reduced the post-exercise decline in forced expiratory flow in 1 second (FEV<sub>1</sub>) by 48% (95% CI: 33% to 64%).<sup>23</sup> Thus, according to the NCCAM and the Cochrane Library, these treatments fall into the CAM field, and, on the basis of consistent positive RCT findings, they are EBM treatments.

### **Why are the three preceding examples part of CAM and not part of current mainstream medicine?**

In the preceding discussion, we showed that EBM and CAM are not opposites, but rather they are concepts pointing at different dimensions (Table 1). In our view, the opposite of CAM is ‘mainstream medicine’, which is not the same as EBM. For example, ‘mechanistic reasoning’, i.e. theoretical argumentation, has been an essential part of mainstream medicine for two millennia, and, in many time periods, theory has been much more important than empiricism.<sup>24-26</sup> However, mechanistic reasoning is explicitly de-emphasized by EBM, which strongly favours RCTs.<sup>2,3</sup>

EBM originated from the concern that numerous ineffective treatments had been adopted by mainstream medicine, and the RCT was viewed as the most reliable method with which to identify the treatments that actually work. However, there is an opposite problem ‘when an efficacious treatment for a certain disease is ignored or rejected because it does not make sense in the light of accepted theories of disease mechanism and drug action’.<sup>24</sup> Goodwin and Goodwin (1984) named this phenomenon ‘the tomato effect’. With this name, they were referring to the historical background of the United States, where tomatoes were considered poisonous for a few centuries

after they had been widely adopted in European kitchens. The idea of tomatoes being poisonous was based on theoretical argumentation: the tomato belongs to the *Solanaceae* family, which includes several deadly poisonous plants; therefore tomatoes must also be poisonous.<sup>24</sup>

Goodwin and Goodwin<sup>24,25</sup> gave several examples of medical ‘tomatoes’: treatments that were rejected because they did not fit prevailing theories. Furthermore, in some cases, the effective treatment had been used for a long time, but changes in the theories of pathogenesis led to the rejection of the treatments because they no longer made any sense, even though the clinical effects did not disappear with the changes in theories.

With the recent explosion in the molecular level understanding of the origin of diseases, the importance of theoretical explanations has not been decreasing in mainstream medicine. However, if the emphasis on theory is too strong, the evaluation of treatments focuses on theoretical explanations, and not on the empirical question of whether a treatment works or not.<sup>24-26</sup>

In mainstream medicine, the dominant theory of vitamins is that their purpose in the body is to prevent deficiency diseases, and thereby their other use belongs to the CAM field.<sup>17,26</sup> Nevertheless, there are biological rationalisations to explain some effects of vitamins unrelated to treating deficiencies. For example, exercise causes oxidative stress, and vitamin C, as an antioxidant, could protect against such stress. Consequently, the effects of vitamin C may be particularly pronounced during exercise, which is the factor common in two of the aforementioned effects.<sup>22,23</sup> However, such an explanation is rather vague when compared with the explanations of the effects of modern drugs that bind to well-defined specific receptors.

In addition to the emphasis on theories, Goodwin and Goodwin mentioned another reason for the ‘tomatoes’ in medicine: ‘if a treatment bypasses the medical establishment and is sold directly to the public ... the temptation in the medical community is to accept uncritically the first bad news that comes along’.<sup>24,26</sup> This seems to be a problem also with the three examples given in the preceding discussion.

Two influential reviews on vitamin C and the common cold in the 1970s concluded that vitamin C is useless for colds, and the reviews were extensively cited. However, the reviews were shown to be flawed over a decade ago.<sup>27,28</sup> Apparently the conclusions of the reviews fitted so well with the theory in mainstream medicine that the validity of the reviews was not considered when they were published. Cochrane reviews are usually restricted to RCTs, which does not imply that they are always trustworthy. Those on zinc and the common cold, and on vitamin C and asthma,



were shown to have severe errors in the extraction of data and in the data analysis, and these errors invalidate the conclusions of the reviews.<sup>29-31</sup>

**CAM covers diverse treatments that have little in common,  
except for being outside mainstream medicine**

There is no unifying theory behind all of the diverse CAM treatments. We agree with Wolpe<sup>14</sup> (see the preceding discussion), according to whom CAM is best understood as a ‘residual category’, in other words, a category of treatments outside mainstream medicine. In our view, many or most CAM treatments are not credible from the scientific point of view. Nevertheless, as shown in the preceding discussion, the fact that a specific treatment falls into the CAM field does not prove that it is ineffective.

Some CAM treatments, such as homeopathy, are fundamentally incompatible with science. We do not believe that such treatments will ever become part of mainstream medicine, even if some RCT findings have been positive. Publication bias and methodological flaws are far more plausible explanations for the positive RTC results related to homeopathy than errors in basic theories of chemistry are. When there is a very strong theory, empiricism is secondary. This statement not only applies to the rejection of homeopathy, but also, for example, to the use of antibiotics for severe infections irrespective of whether RCTs have been carried out or not.

Some treatments, such as the three aforementioned examples, may belong to the CAM field for historical reasons and preconceptions within mainstream medicine. We assume that, sooner or later, such treatments will be included in mainstream medicine instead of CAM.

As noted in the beginning of this essay, the journal Evidence-Based Complementary and Alternative Medicine (eCAM) has announced that it ‘seeks to understand the sources and to encourage rigorous research in this new, yet ancient world of complementary and alternative medicine’.<sup>1</sup> To explore the meaning of the term ‘evidence-based’ in the journal, we reviewed 100 consecutive papers that were published in eCAM in Autumn 2013. We found out that only 10% of them reported the results of RCTs and about 50% reported the results of animal or in vitro experiments. In this respect the term ‘evidence-based’ seems to be more of a marketing term to increase the credibility of the journal<sup>1</sup> than a signal of adherence to EBM reasoning.

## Conclusions

The purpose of our essay is not to provide general support to CAM treatments. Instead, the purpose is to point out that the demarcation line between CAM and mainstream medicine is not simply defined by the question of whether a treatment works or not. The demarcation line is also defined by historical and political grounds, and by the theories of disease aetiologies and treatment mechanisms. Mainstream medicine does not equal EBM, which emphasizes RCTs as the source of valid information on treatment efficacy. Consequently, some treatments that currently lie outside mainstream medicine can therefore be evidence-based.

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